

S/N: 09/808,512  
Reply to Office Action of October 22, 2003

Atty Dkt No. UOM 0193 PUS

### **Remarks**

Claims 1-31 were pending in this application. Claims 1 and 12-13 have been amended, claims 8 and 19 have been canceled, and no claims have been added.

Applicants wish to thank the Examiner for extending the courtesy of a telephone interview on December 22, 2003 wherein the Khorsandian and Hinkle references were discussed. Reconsideration of this application is respectfully requested in light of the above amendments and the following remarks.

#### **Allowed Claims**

Applicants appreciate the Examiner's indication that claims 24-31 have been allowed.

#### **Rejection of Claims 1-3 and 5-12**

##### **Under 35 U.S.C. § 103(a) Over Khorsandian and Fukunaga**

Claims 1-3 and 5-12 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,146,913 issued to Khorsandian et al. ("Khorsandian") in view of U.S. Patent No. 6,003,511 issued to Fukunaga et al. ("Fukunaga"). In response, Applicants have amended claims 1 and 12 to more particularly point out and distinctly claim the subject matter of the invention.

Specifically, claim 1 has been amended to recite that the base includes "a generally continuous, annular inlet opening ... wherein the inlet opening has an outer diameter of approximately 15 mm for connecting with a standard breathing tube external to the patient." Claim 12 has been similarly amended to recite "a generally continuous, annular connector projecting from the base rear surface" where the connector proximal end has "an outer diameter of approximately 15 mm for receiving a standard breathing tube over the connector proximal end." Directly teaching away from Applicants' claimed invention, Khorsandian discloses a holder for oro-intubation having a collet 56 with a center hole 58 that is sized to receive a tracheal tube 12 therethrough and is *split* to lock the tracheal tube 12 without closing

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off the tube 12 if the collet 56 is over tightened (*see* Khorsandian, col. 5, lines 5-14; FIGS. 2A and 2C). Due to split collet 56, Khorsandian's holder clearly cannot function to deliver gas into the oral cavity of a patient via an externally connected breathing tube as in Applicants' claimed invention.

Furthermore, Khorsandian fails to recognize the problem solved by Applicants' invention, namely providing a pacifier which can be quickly and securely connected to a standard breathing tube remaining external to the body for delivering gases to a patient via the oral cavity. Instead, Khorsandian discloses a holder for an intubation tube (i.e., endotracheal tube, gavage feeding tube, etc.) which is threaded through the holder and down a patient's throat (*see* Khorsandian, col. 5, lines 19-30; FIG. 1A), and does not disclose or suggest the delivery of gases in any other manner. Applicants further assert that there is no motivation or suggestion to combine Khorsandian and Fukunaga, again because Khorsandian is directed to the delivery of gases or liquids into the *trachea or esophagus via intubation*, not the delivery of gases into the *oral cavity via an externally connected breathing tube*. These arguments also apply to other references directed to positioners for oro-intubation (e.g., U.S. Patent No. 2,693,182 issued to Phillips).

Therefore, Applicants believe that claims 1 and 12 are patentably distinguishable over the combination of Khorsandian and Fukunaga. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of these claims and their corresponding dependent claims under 35 U.S.C. § 103(a).

#### **Rejection of Claim 8**

##### **Under 35 U.S.C. § 103(a) Over Khorsandian and Stevens**

Claim 8 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Khorsandian in view of U.S. Patent No. 5,810,000 issued to Stevens ("Stevens"). Claim 8 has been canceled herein, such that this rejection is now obviated.

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**Rejection of Claims 13-16 and 18-23  
Under 35 U.S.C. § 103(a) Over Hinkle**

Claims 13-16 and 18-23 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,896,666 issued to Hinkle ("Hinkle"). In response, Applicants have amended claim 13 to more particularly point out and distinctly claim the subject matter of the invention.

Specifically, claim 13 has been amended to recite that the nipple member has "a single outlet opening provided in a distal end thereof ... such that anesthetic gas can flow through the base and the nipple member for delivery via the outlet opening exclusively into the oral cavity of the patient." This feature of Applicants' invention is neither disclosed nor suggested by Hinkle, and in fact Hinkle teaches away from this feature of Applicants' invention. As discussed previously in the Amendment dated September 17, 2002, Hinkle discloses that "anesthetic gas can be introduced through the opening 28 where it will pass through passageway 34 of the pacifier through apertures 38 into the air space 22 so that the wearer can breathe the gas through the nose" (*see* col. 4, lines 57-61). The only use that Hinkle discloses for hole 36 at the tip of pacifier 12 is that "a catheter can be inserted through opening 28 of the mask and through passageway 34 so that the end of the catheter is positioned between the apertures 38 and hole 36 and suction can be provided through hole 36" (*see* Hinkle, col. 4, line 65- col. 5, line 1). As known in the art, anesthesia and other gases inhaled via the nasal passages are naturally filtered, thereby reducing the amount of gas which reaches the lungs of the patient over a given time. This may result in a longer time required for inhalation therapy to be performed, and possibly less consistent and less efficacious outcomes (*see* p. 2, line 30 - p. 3, line 10).

Therefore, Applicants believe that claim 13 is patentably distinguishable over Hinkle. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of this claim and its corresponding dependent claims under 35 U.S.C. § 103(a).

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**Rejection of Claim 17**

**Under 35 U.S.C. § 103(a) Over Hinkle and Gross**

Claim 17 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Hinkle in view of U.S. Patent No. 5,823,184 issued to Gross ("Gross"). Claim 17 depends from and contains all the limitations of independent claim 13 which, for the reasons stated above, is believed to be patentably distinguishable over Hinkle, either alone or in combination with Gross. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 17 under 35 U.S.C. § 103(a).

**Rejection of Claim 21**

**Under 35 U.S.C. § 103(a) Over Hinkle and Stevens**

Claim 21 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Hinkle in view of U.S. Patent No. 5,810,000 issued to Stevens ("Stevens"). Claim 21 depends from and contains all the limitations of independent claim 13 which, for the reasons stated above, is believed to be patentably distinguishable over Hinkle, either alone or in combination with Stevens. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 21 under 35 U.S.C. § 103(a).

### Conclusion

In summary, Applicants believe that the claims, as amended, now meet all formal and substantive requirements and that the case is in appropriate condition for allowance. Accordingly, such action is respectfully requested. If a telephone conference would expedite allowance of the case or resolve any further questions, such a call is invited at the Examiner's convenience.

Respectfully submitted,

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